UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

FOO YUAN FOOD PRODUCTS COMPANY, INC., HSING CHUANG (aka George Chuang), and SUSAN CHUANG,

Defendants.

COMPLAINT

Civil Action No.
18-CV-

CV 18-4689
VITALIANO, J.
POLLAK, M.J.

Plaintiff, the UNITED STATES OF AMERICA, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), hereby alleges as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Foo Yuan Food Products Company, Inc., Hsing Chuang and Susan Chuang (collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), and

B. 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

PARTIES

4. Defendant Foo Yuan Food Products Company, Inc. ("Foo Yuan") is a privately held New York corporation with its principal place of business at 2301 Borden Ave., Long Island City, NY 11101 (the "Facility"), within the jurisdiction of this Court.

5. Defendant Hsing Chuang, also known as "George" Chuang, is the Owner and President of Foo Yuan. He is the most responsible person at the company. Mr. Chuang is directly responsible for Foo Yuan's day-to-day operations, including product ordering, receiving, processing, packaging, storing, marketing, and distribution, facility maintenance, and sanitation. He is responsible for preventing, detecting, and correcting violations. He also has the authority to hire and fire employees. He performs his duties at 2301 Borden Ave., Long Island City, NY 11101, within the jurisdiction of this court.

6. Defendant Susan Chuang is the Secretary of Foo Yuan, and defendant Hsing Chuang's daughter. Ms. Chuang has completed a Hazard Analysis and Critical Control Point ("HACCP") training course, and is responsible for Foo Yuan's HACCP responsibilities. At all times relevant to the complaint, Ms. Chuang has held herself out as a company representative with knowledge of HACCP issues and authority to address HACCP deficiencies. She performs her duties at 2301 Borden Ave., Long Island City, NY 11101, within the jurisdiction of this court.

7. Defendants prepare, manufacture, process, pack, hold, and distribute refrigerated and frozen ready-to-eat ("RTE") fish balls, fried fish cakes, and fried fish balls, all packaged in reduced oxygen packaging ("ROP").

8. Defendants directly distribute 40% of their products to Summit Import Corporation, a wholesale distributor located in Summit Place, NJ. Defendants also receive raw fish from a New York distributor that imports its fish from Canada.

DEFENDANTS' VIOLATIONS OF THE ACT

Defendants' Food is Adulterated

9. The Act and its implementing regulations require a seafood processor to control the risk of *Clostridium botulinum* ("*C. bot*") and *Listeria monocytogenes* ("*L. mono*") formation if the bacteria are reasonably likely to grow in the processor's seafood products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(a)-(c).

10. *C. bot* is an anaerobic bacterium, meaning that it thrives in oxygen-free environments. All people are susceptible to *C. bot*'s neurotoxin that *C. bot* spores can produce in food. Ingesting even a small amount of this neurotoxin can cause botulism. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if it is not treated promptly.

11. *C. bot* is a pathogen that is widely distributed in nature and may be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. bot* can survive cooking. *C. bot* can also survive in food that has been incorrectly or minimally processed. Certain strains of *C. bot*, called proteolytic strains, produce offensive odors and tastes in food products, and can grow at temperatures as low as 50°F. In contrast, non-proteolytic strains of *C. bot* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous

because they can grow and produce toxin at refrigeration temperatures (as low as 38°F), rendering a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot* can occur at temperatures above 38°F. In foods that rely on refrigeration to inhibit the growth of *C. bot.*, seafood processors must employ appropriately rapid cooling processes after cooking to prevent pathogen growth and toxin formation.

12. In addition, seafood packaged in ROP is particularly susceptible to *C. bot* toxin growth and production. Although ROP extends the products' shelf life by inhibiting the growth of many aerobic bacteria and molds, it also can facilitate the growth of anaerobic organisms, like *C. bot.*, that thrive in conditions with little or no oxygen. Thus, *C. bot* toxin may grow in ROP-packaged product before other bacteria and molds would provide visible evidence to alert the consumer that the product has spoiled.

13. *L. mono* is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia in the newborn.

14. Unlike many other foodborne microbes, *L. mono* can adapt and grow at refrigeration temperatures or under other adverse conditions, such as high-salt or high-acid (low pH) conditions. The presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

15. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and to eliminate niches

where *L. mono* can become established, grow, and persist. Strict in-plant sanitation measures must be taken to eliminate *L. mono* and prevent its proliferation.

16. Defendants' ready-to-eat fish and fishery products are "food" within the meaning of the Act. *See* 21 U.S.C. § 321(f).

17. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health[.]"

18. A seafood processor's failure to comply with the requirements of the seafood HACCP regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

19. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of its fish or fishery products. 21 C.F.R. § 123.6(a). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

20. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

A. Identify critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent,

eliminate, or reduce a food safety hazard to an acceptable level, *see* 21 C.F.R. §§ 123.3(b) and 123.6(c)(2); and

B. Identify critical limits at each CCP, which are the maximum or minimum values within which a physical, biological or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s), *see* 21 C.F.R. §§ 123.3(c) and 123.6(c)(3).

21. A seafood processor must also:

A. Take corrective action whenever a deviation from a critical limit occurs, 21 C.F.R. § 123.7;

B. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented, 21 C.F.R. § 123.8(a);

C. Record its sanitation activities, 21 C.F.R. § 123.11(c), and maintain additional appropriate records, such as documentation of CCPs, corrective actions taken, and HACCP plan verification activities, 21 C.F.R. §§ 123.6-123.9; and

D. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the Current Good Manufacturing Practice ("cGMP") requirements for food, including prevention of cross-contamination from insanitary objects and exclusion of pests, 21 C.F.R. § 123.11(b) and 21 C.F.R. Part 110.

22. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," as defined at 21 C.F.R. §§ 123.3(d) and (e). The seafood HACCP regulations also apply to Defendants because they are seafood "importers" as defined at 21 C.F.R. § 123.3(g).

23. Food is adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with cGMP regulations for food, 21 C.F.R. Part 110. *See* 21 C.F.R. § 110.5(a).

24. During FDA's inspection of Defendants' facilities between December 4, 2017, and January 10, 2018 ("January 2018 inspection"), both defendants Hsing Chuang and Susan Chuang participated as company representatives and provided information to inspectors. During that inspection, FDA investigators documented significant HACCP and cGMP deficiencies. When the inspection ended, FDA investigators issued to Mr. Chuang a List of Inspectional Observations ("Form FDA-483") that included, but was not limited to, the following observations:

A. Failure to identify and list in the HACCP plan critical limits necessary to control hazards that are reasonably likely to occur in each particular product (*see* 21 C.F.R. § 123.6(c)(3));

B. Failure to follow corrective action plans identified in the HACCP plan when a deviation from a critical limit occurs (*see* 21 C.F.R § 123.7(a));

C. Failure to develop and implement a corrective action plan that is appropriate for a particular deviation (*see* 21 C.F.R. § 123.7(b)); and

D. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including failing to prevent cross-contamination from insanitary objects (*see* 21 C.F.R. § 123.11(b)), as evidenced by their failure to comply with the following cGMP requirements:

i. Failure to maintain the cleanliness of food contact sources (*see* 21 C.F.R. § 110.35(d)); and

ii. Failure to ensure that all persons working in direct contact with food, food contact surfaces, and food-packaging materials conform to hygienic practices to protect against food contamination (*see* 21 C.F.R. § 110.10(b)(1)).

25. Defendants violate 21 U.S.C. § 331(a) by causing the introduction or delivery for introduction into interstate commerce of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4).

26. Defendants violate 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more components in interstate commerce.

27. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Such insanitary conditions include:

A. Defendants' failure to comply with the seafood HACCP regulations, 21 C.F.R. Part 123, by, among other deficiencies, failing to adequately control the risk of *C. bot.* and *L.mono* growth and toxin formation in susceptible fish and fishery products and failing to monitor sanitation conditions and practices during processing with sufficient frequency; and

B. Defendants' failure to implement effective sanitation controls in accordance with food cGMP requirements, 21 C.F.R. Part 110.

DEFENDANTS' HISTORY OF VIOLATIONS

28. Several of the cGMP and HACCP deficiencies observed during FDA's January 2018 inspection (*see infra* ¶ 24) are the same as or similar to those observed by FDA during

previous inspections of Defendants' facility that occurred between June 14, 2016 and July 14, 2016 ("July 2016 inspection"), and October 14-20 2014 ("October 2014 inspection").

29. During the October 2014 inspection, defendants Hsing Chuang and Susan Chuang participated as company representatives and provided information to inspectors. During that inspection, FDA investigators documented significant deficiencies. At the close of this inspection, FDA investigators issued to Mr. Chuang a Form FDA-483, that included the following observations:

A. Failure to have a HACCP plan that lists the food safety hazards that are reasonably likely to occur (*see* 21 C.F.R. § 123.6(c)(1)); and

B. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with cGMP (*see* 21 C.F.R. § 123.11(b)).

30. Following the October 2014 inspection, defendant Susan Chuang prepared, and provided to the FDA, a HACCP plan.

31. Thereafter, on May 28, 2015, FDA issued a Warning Letter notifying defendants Foo Yuan and Hsing Chuang that they were in violation of seafood HACCP and cGMP regulations, causing their products to be adulterated under the Act. The Warning Letter cautioned Foo Yuan and Mr. Chuang that if they failed to promptly correct their violations, FDA may pursue further regulatory action, including an injunction.

32. During the July 2016 inspection, defendant Hsing Chuang participated as a company representative and provided information to inspectors. During that inspection, FDA investigators documented significant HACCP and cGMP deficiencies. At the close of this inspection, FDA investigators issued to Mr. Chuang a Form FDA-483, that included, but was not limited to, the following observations:

A. Failure to identify and list in the HACCP plan critical limits necessary to control hazards that are reasonably likely to occur in particular products (*see* 21 C.F.R. § 123.6(c)(3));

B. Failure to list one or more CCPs that are necessary for each of the identified food safety hazards (*see* 21 C.F.R. § 123.6(c)(2));

C. Failure to develop and implement a corrective action plan that is appropriate for a particular deviation (*see* 21 C.F.R. § 123.7(b)); and

D. Failure to monitor sanitation conditions and practices during processing with sufficient frequency to ensure compliance with cGMP (*see* 21 C.F.R. § 123.11(b)).

33. Following the July 2016 inspection, defendant Susan Chuang met with the FDA on Foo Yuan's behalf at a regulatory meeting at the New York District Office on May 3, 2017. At the meeting, FDA representatives and Ms. Chuang discussed all of the Defendants' previous deficiencies and their repeated failures to correct these deficiencies, and Ms. Chuang committed to correcting the deficiencies at Foo Yuan identified by the FDA.

34. Defendant Susan Chuang responded to the Forms FDA-483 and Warning Letter, acknowledging the deficiencies and promising to take corrective action. As evidenced by the repeated observations of HACCP and cGMP deficiencies during FDA's January 2018 inspection, Mr. Chuang and Ms. Chuang have failed to take effective measures to bring their seafood processing operations into compliance with the law.

35. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

COUNT I
(For violations of 21 U.S.C. § 331(a))

36. The United States realleges and incorporates by reference Paragraphs 1 through 35 of this Complaint as though fully set forth herein.

37. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 21 U.S.C. § 331(a) by introduction or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. § 342(a)(4).

38. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health.

39. Upon a showing that the Defendants are violating 21 U.S.C. § 331, the United States may obtain a permanent injunction enjoining such violation. 21 U.S.C. § 332(a).

40. As a result of the foregoing, Defendants' conduct should be enjoined pursuant to 21 U.S.C. § 332.

COUNT II
(For violations of 21 U.S.C. § 331(k))

41. The United States realleges and incorporates by reference Paragraphs 1 through 40 of this Complaint as though fully set forth herein.

42. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 21 U.S.C. § 331(k) by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more components in interstate commerce.

43. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health.

44. Upon a showing that the Defendants are violating 21 U.S.C. § 331, the United States may obtain a permanent injunction enjoining such violation. 21 U.S.C. § 332(a).

45. As a result of the foregoing, Defendants' conduct should be enjoined pursuant to 21 U.S.C. § 332.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff United States of America respectfully requests that, pursuant to 21 U.S.C. § 332(a) and the inherent power of the Court, that the Court issue an Order and Final Judgment:

I. ordering Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), to cease receiving, preparing, processing, packing, holding, or distributing articles of food, at or from the Facility or at any other current or future location, unless and until Defendants bring their receiving, preparing, processing, packing, holding, and food distribution into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. permanently restraining and enjoining Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), from directly or indirectly

violating 21 U.S.C. §§ 331(a) or (k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), or by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, adulterated articles of food into interstate commerce, within the meaning of 21 U.S.C. § 342(a)(4);

III. authorizing FDA to inspect Defendants' places of business and all records relating to the receiving, preparing, processing, packing, holding, and food distribution to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished;

IV. awarding Plaintiff costs incurred in pursuing this action, including the costs of investigation to date, and

V. for such other equitable relief as the Court deems just and proper.

DATED this 20th day of August, 2018.

Respectfully submitted,

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